## IAP5 Rec'd PCT/PTO 28 SEP 2006

PTO/SB/08a/b (07-06)

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				Application Number	NEW 0/50/507	
11	<b>IFORMATION</b>	I DI	SCLOSURE	Filing Date	September 28, 2006	
S	STATEMENT BY APPLICANT			First Named Inventor	Kazutaka IKEDA	
				Art Unit	NA 1634	
(Use as many sheets as necessary)			s necessary)	Examiner Name	Matakakasiganata ST Kapus	hoc
Sheet	1	of	1	Attorney Docket Number	0649-1380PUS1	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	

FOREIGN PATENT DOCUMENTS						
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		NON PATENT LITERATURE DOCUMENTS	
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	CA	Shi, J. et al., Sequence variations in the mu-opioid receptor gene (OPRM1) assocaited with human addiction ot heroin, Hum Mutat, 2002, Vol. 19, No. 4, pages 459 to 460.	ISR
	СВ	Szeto, C.Y. et al., Association between mu opioid receptor gene polymorphisms and Chinese heroin addicts, Neuroreport, 2001, Vol. 12, No. 6, pages 1103 to 1106.	ISR
	CC	Gelernter, J. et al., Genetics of two mu opioid receptor gene (OPRM1) exon I polymorphisms: population studies, and allele frequencies in alcohol - and drug-dependent subjects, Mol.Phychiatry, 1999, Vol. 4, No. 5, pages 476 to 483.	ISR
	CD	HIROTA, T. et al., Sequence variability and candidate gene analysis in two cancer patients with complex clinical outcomes during morphine therapy, Drug Metab.Dispos., 2003, Vol. 31, No. 5, pages 677 to 680.	ISR
	CE	Hoehe, M.R. et al., Sequence variability and candidate gene analysis in complex disease: association of mu opioid receptor gene variation with substance dependence, Hum.Mol.Genet., 2000, Vol. 9, No. 19, pages 2895 to 2908.	ISR
	CF	Uhl, G.R. et al., The mu opiate receptor as a candidate gene for pain: polymorphisms, variations in expression, nociception, and opiate responses, Proc.Natl.Acad.Sci.USA, 1999, Vol. 96, No. 14, pages 7752 to 7755.	ISR
	CG	Mayer, P. et al., Allelic and somatic variations in the endogenous opioid system of humans, Pharmacol.Ther., 2001, Vol 91, No. 3, pages 167 to 177.	ISR

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Examiner /Stephen Kapushoc/	Date Considered	05/06/2009
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